

In the Claims:

The current claim set of the application is presented below. Indications as to the status of the claims ("original", "currently amended", "cancelled", "new", etc.) appear in parentheses after the claim number. Deletions are identified in bold with double brackets and strikethrough (e.g. ~~[[deletion]]~~) and new text is identified in bold with underlining (e.g. new language).

1.- 25. (Cancelled)

26. (Currently amended) A gastrointestinal lead adapted to be implanted within the body at a site of the GI tract to conduct electrical stimulation from an implantable or external gastrointestinal stimulator to the site and to conduct electrical signals of the GI tract from the site to the implantable or external gastrointestinal stimulator comprising:
an elongated lead body extending from a lead body proximal end to a lead body distal end;
an electrode head formed at the lead body distal end having a plate adapted to bear against the serosa, the electrode head supporting a first stimulation/sense electrode;
a first lead connector element at the lead body proximal end;
a first lead conductor enclosed within the lead body and electrically coupled to the first stimulation/sense electrode and the first lead connector element; and
an active fixation mechanism extending away from the plate of the electrode head shaped to penetrate through the serosa and into the muscularis externa upon application of force to the electrode head to draw the plate against the serosa and operatively contact the first stimulation/sense electrode with the GI tract wall, whereupon the plate inhibits further advancement of the active fixation mechanism and perforation of the GI tract wall and the active fixation mechanism inhibits dislodgement of the first stimulation/sense electrode from operative contact with the GI tract wall ~~[[The gastrointestinal lead of Claim 1]]~~, wherein:

the active fixation mechanism comprises an inner helix and an outer helix, the inner helix comprising one or more coil turn extending from an inner helix fixed end and an inner helix free end adapted to penetrate through the serosa, and the outer helix comprising one or more coil turn

extending from an outer helix fixed end and an outer helix free end adapted to penetrate through the serosa; and further comprising:

means for supporting the inner and outer helixes in co-axial relation extending away from the electrode plate

means for rotating the inner and outer helixes to advance the inner and outer helixes into the muscularis externa until the plate is drawn against the serosa.

27. (Original) The gastrointestinal lead of Claim 26, wherein the inner and outer helixes have an axial length enabling a depth of penetration from the plate in the range of 1 mm to 15 mm when the site comprises the antrum of the stomach wall or in the range of 1 mm to 10 mm when the site comprises corpus or fundus of the stomach wall to ensure that the inner and outer helix free ends do not extend substantially through the stomach wall.

28. (Original) The gastrointestinal lead of Claim 26, wherein:
the inner helix free end is electrically connected with the first lead conductor to function as the first stimulation/sense electrode; and further comprising:
a second lead connector element at the lead body proximal end; and
a second lead conductor enclosed within the lead body and electrically coupled to the outer helix free end to function as a second stimulation/sense electrode.

29. (Original) The gastrointestinal lead of Claim 26, wherein:
the elongated lead body encloses a stylet lumen extending into the electrode head; and
the rotating means comprises a rotatable mechanism fitted into the electrode head and attached to the inner and outer helix fixed ends to extend the inner and outer helixes orthogonally to the plate, the rotatable mechanism adapted to be engaged by a stylet advanced through the stylet lumen, whereby the rotatable mechanism is rotated by the stylet to rotate the inner and outer helixes and advance the inner and outer helix free ends through the serosa and into the muscularis externa until the plate is drawn against the serosa.

30-39. Cancelled

40. (Currently amended) A method of stimulating a site of the GI tract with electrical stimulation from an implantable or external gastrointestinal stimulator and of conducting electrical signals of the GI tract from the site to the implantable or external gastrointestinal stimulator comprising:

surgically accessing the serosa of the GI tract at the site to locate an electrode head of a medical electrical lead oriented to the serosa, the medical electrical lead extending between a connector at a lead body proximal end to an electrode head at a lead body distal end, the electrode head supporting a first electrode and an active fixation mechanism extending from a plate;

perforating the serosa with the active fixation mechanism of the electrode head;
advancing the active fixation mechanism into the muscularis externa to apply the first electrode into operative relation with the GI tract wall and until the plate bears against the serosa to inhibit further advancement of the active fixation means and perforation of the GI tract wall; and

connecting the connector at the lead body proximal end with an implantable or external stimulator to enable conduction of electrical signals through a lead conductor enclosed within the lead body and electrically coupled to the first stimulation/sense electrode and the connector, whereby the active fixation mechanism inhibits dislodgement of the first stimulation/sense electrode from operative relation with the GI tract wall ~~[[The method of Claim 31,]]~~ wherein:

the elongated lead body encloses a stylet lumen;

the electrode head comprises:

a first helix comprising one or more coil turn extending from a helix fixed end and a helix free end and having a first helix axis;

a second helix comprising one or more coil turn extending from a helix fixed end and a helix free end and having a second helix axis co-axially aligned with the first helix axis;

a rotatable mechanism fitted into the electrode head and attached to the first and second helix fixed ends to extend the helix axes orthogonally to the plate;

the perforating step comprises penetrating the serosa with the first and second helix free ends; and

the advancing step comprises inserting a stylet into the stylet lumen to engage the rotatable mechanism and rotating the stylet to rotate the first and second helices to advance each coil turn into the muscularis externa until the plate is drawn against the serosa.

41-79. Cancelled

80. (Currently amended) ~~[[The gastrointestinal lead of Claim 56, wherein:]]~~ A system providing gastrointestinal sensing and/or stimulation comprising:

a gastrointestinal lead comprising an elongated gastrointestinal lead body comprising:

an elongated lead body extending from a lead body proximal end to a lead body distal end;

an electrode head formed at the lead body distal end having a plate adapted to bear against the serosa, the electrode head supporting a first stimulation/sense electrode;

a first lead connector element at the lead body proximal end;

a first lead conductor enclosed within the lead body and electrically coupled to the first stimulation/sense electrode and the first lead connector element; and

an active fixation mechanism extending away from the plate of the electrode head shaped to penetrate through the serosa and into the muscularis externa upon application of force to the electrode head to draw the plate against the serosa and operatively contact the first stimulation/sense electrode with the GI tract wall, whereupon the plate inhibits further advancement of the active fixation mechanism and perforation of the GI tract wall and the active fixation mechanism inhibits dislodgement of the first stimulation/sense electrode from operative contact with the GI tract wall, the active fixation mechanism comprising ~~[[comprises]]~~ an inner helix and an outer helix, the inner helix comprising one or more coil turn extending from an inner helix fixed end and an inner helix free end adapted to penetrate through the serosa, and the outer helix comprising one or more coil turn extending

from an outer helix fixed end and an outer helix free end adapted to penetrate through the serosa;
and further comprising:

means for supporting the inner and outer helices in co-axial relation extending away from the electrode plate,

means for rotating the inner and outer helices to advance the inner and outer helices into the muscularis externa until the plate is drawn against the serosa;

deploying means for deploying the active fixation mechanism extending away from the plate of the electrode head and penetrating through the serosa and into the muscularis externa to draw the plate against the serosa and operatively contact the stimulation/sense electrode with the GI tract wall, whereby the plate inhibits further advancement of the active fixation mechanism and perforation of the GI tract wall, and the active fixation mechanism inhibits dislodgement of the stimulation/sense electrode from operative contact with the GI tract wall; and

an implantable or external gastrointestinal stimulator having a gastrointestinal stimulator connector coupled with the lead connector assembly to conduct electrical stimulation from the implantable or external gastrointestinal stimulator between the first and second sites of the GI tract and to conduct electrical signals of the GI tract from the first and second sites to the implantable or external gastrointestinal stimulator.

81. (Original) The system of Claim 80, wherein the inner and outer helices have an axial length enabling a depth of penetration from the plate in the range of 1 mm to 15 mm when the site comprises the antrum of the stomach wall or in the range of 1 mm to 10 mm when the site comprises corpus or fundus of the stomach wall to ensure that the inner and outer helix free ends do not extend substantially through the stomach wall.

82. (Original) The system of Claim 80, wherein:
the inner helix free end is electrically connected with the first lead conductor to function as the first stimulation/sense electrode; and further comprising:
a second lead connector element at the lead body proximal end; and

a second lead conductor enclosed within the lead body and electrically coupled to the outer helix free end to function as a second stimulation/sense electrode.

83. (Original) The system of Claim 80, wherein:
the elongated lead body encloses a stylet lumen extending into the electrode head; and
the rotating means comprises a rotatable mechanism fitted into the electrode head and attached to the inner and outer helix fixed ends to extend the inner and outer helices orthogonally to the plate, the rotatable mechanism adapted to be engaged by a stylet advanced through the stylet lumen, whereby the rotatable mechanism is rotated by the stylet to rotate the inner and outer helices and advance the inner and outer helix free ends through the serosa and into the muscularis externa until the plate is drawn against the serosa.